WHAT CAN PUBLIC HEALTH LABS DO TO IMPROVE BIOSAFETY IN OUR NATIONS LABS?

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Biosafety Topics Are In the Forefront

Review of CDC Anthrax Lab Incident

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Director
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

CDC
SAFER • HEALTHIER • PEOPLE™

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UNDER EMBARGO until NOON, August 15, 2014

Report on the Inadvertent Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1

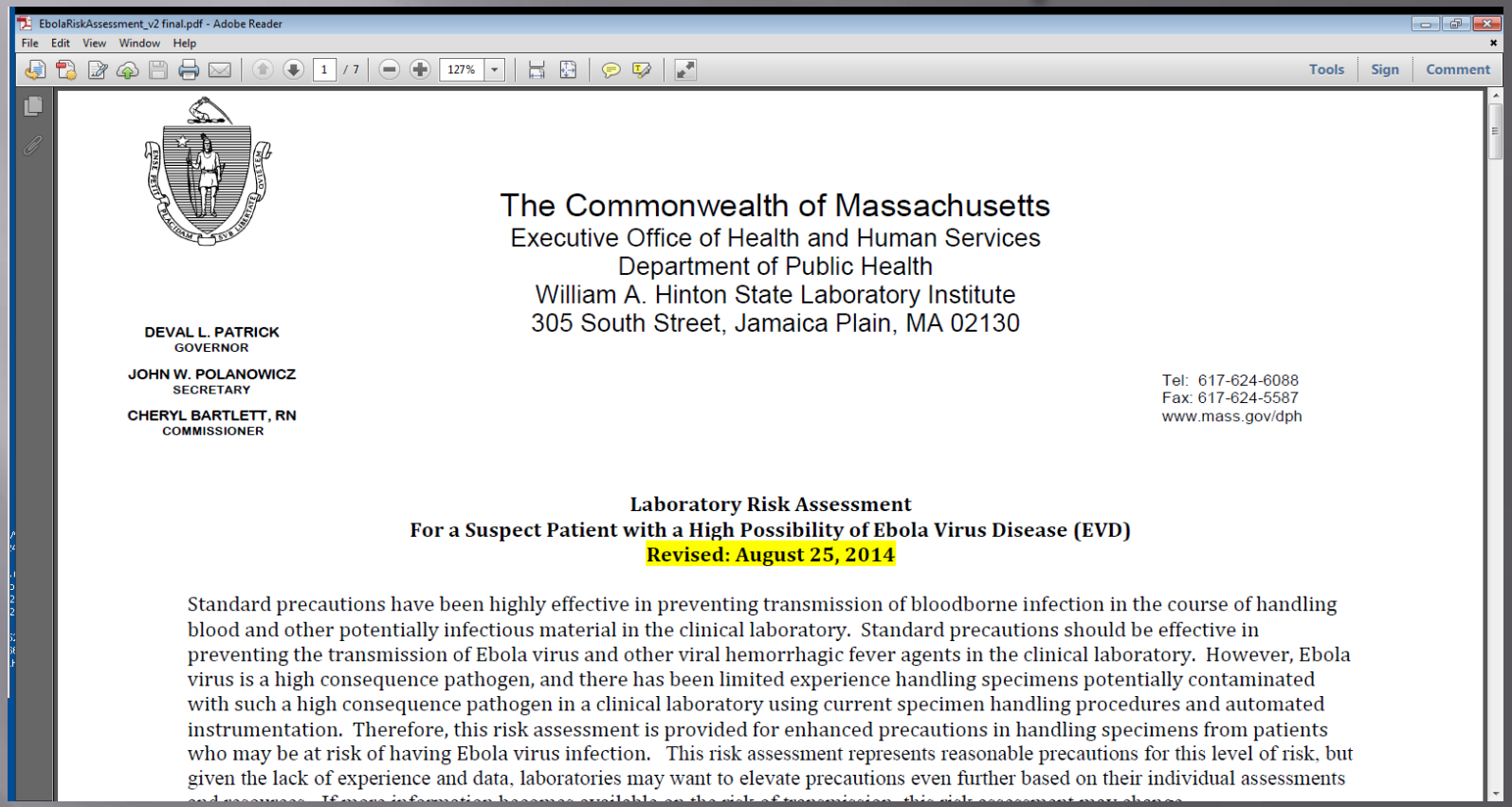
Centers for Disease Control and Prevention

8/15/2014

How MA SPHL prepared for ebola testing

- Performed a risk assessment
- Wrote the safety procedure
- Trained staff and documented competency
- Met with other staff to allay fears
- Validated ebola test procedure
- Went into “Incident Command” mode and met daily for 15 min with leadership team
- Served as expert resource to clinical labs through FAQ’s, risk assessment templates, emails, conference calls, phone calls

MA SPHL provided clinical labs a risk assessment template


EbolaRiskAssessment_v2 final.pdf - Adobe Reader

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Laboratory Risk Assessment
For a Suspect Patient with a High Possibility of Ebola Virus Disease (EVD)
Revised: August 25, 2014

Standard precautions have been highly effective in preventing transmission of bloodborne infection in the course of handling blood and other potentially infectious material in the clinical laboratory. Standard precautions should be effective in preventing the transmission of Ebola virus and other viral hemorrhagic fever agents in the clinical laboratory. However, Ebola virus is a high consequence pathogen, and there has been limited experience handling specimens potentially contaminated with such a high consequence pathogen in a clinical laboratory using current specimen handling procedures and automated instrumentation. Therefore, this risk assessment is provided for enhanced precautions in handling specimens from patients who may be at risk of having Ebola virus infection. This risk assessment represents reasonable precautions for this level of risk, but given the lack of experience and data, laboratories may want to elevate precautions even further based on their individual assessments

MA SPHL fielded many questions on conference calls and by emails from clinical labs to help them plan for a suspect patient.

Risk Assessment: Predict, Identify, & Mitigate Risk

Procedure	Potential Hazards	Control	Comment
Preparation of Specimens for Testing	Aerosolization/ Splash/ Splatter	-Minimize the number of workers handling the specimens. -Use PPE: fluid resistant back-closing gown, double gloves, N95 respirator and goggles, or full face shield, (eyes and mucous membranes covered). -Limit the traffic around the BSC.	-No exposed skin inside the BSC. -Immediately change gloves if contamination is visible or suspected. -Bring all necessary material into the BSC before starting to work. -Do not enter and re-enter BSC once specimen processing begins.

How Indiana worked with Clinical Labs to prepare for ebola testing

- Ebola hotline for clinical labs to provide one-on-one consultation and answer specific questions about specimen collection, PPE requirements, packaging and shipping etc.

How New York worked with Clinical Labs to prepare for ebola testing

- Developed two comprehensive guidance documents for testing of suspect or positive patients
- Numerous individual and group phone calls, conferences and meetings
- On-site surveys to assess and provide guidance
- Guidance documents on regulated medical waste

Wadsworth Center
NEW YORK STATE DEPARTMENT OF HEALTH

Perceptions post ebola

- There is a lack of fundamental knowledge about biosafety in the lab community
- The culture of biosafety is weak
- Most clinical labs have never performed a risk assessment
- Labs are very short staffed and working on biosafety issues is a low priority
- It is difficult to provide expert opinion because of the different equipment in use

CDC: Epidemiology and Laboratory Capacity (ELC) Program – ebola 3 year funding

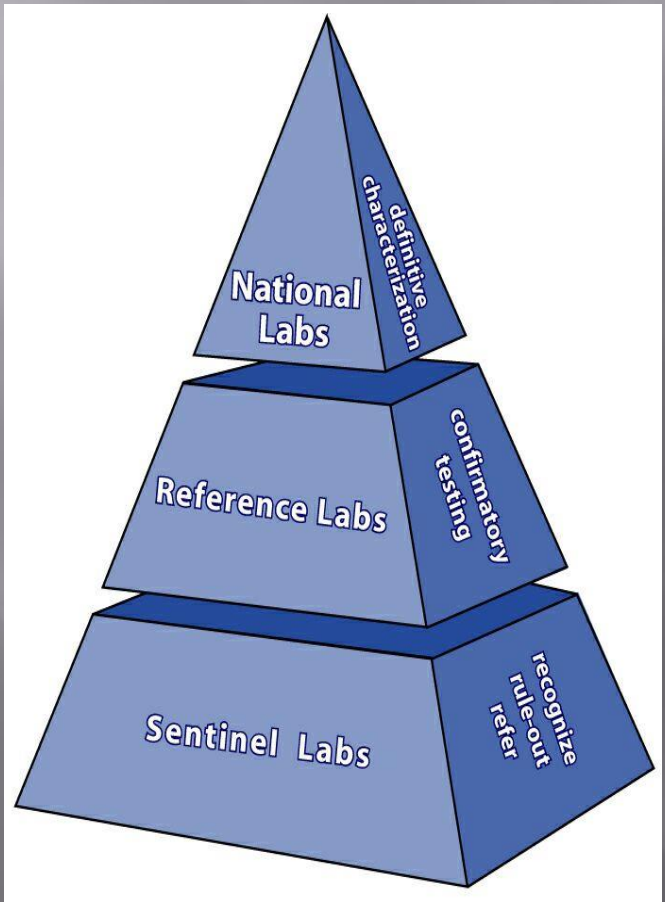
- Activities in the Public Health Lab
  - Biosafety Officer for each PHL
  - Perform risk assessment (RA) of PHL
  - Develop/provide/assure access to tools, guidance, trainings and other educational activities for clinical labs
    - RA templates or models, exercises
  - Implement mitigation strategies based on risk assessment
  - Address gaps identified through RA
  - Work through APHL leadership

CDC: Epidemiology and Laboratory Capacity (ELC) Program – ebola 3 year funding

- Activities for PHL working with Clinical Labs
  - Clinical labs perform RA
  - Address gaps identified in their own RA
  - Identify and implement mitigation strategies

PHL working with sentinel labs

- Modeled after the successful Laboratory Response Network for preparedness



LRN
LABORATORY RESPONSE NETWORK
PARTNERS IN PREPAREDNESS

Draw backs:

- Staff changeover
- Unable to train everyone
- Labs become less interested with time as news worthiness wanes

APHL forms Biosafety and Biosecurity Committee 3-26-15

Proposed Priorities for the Committee:

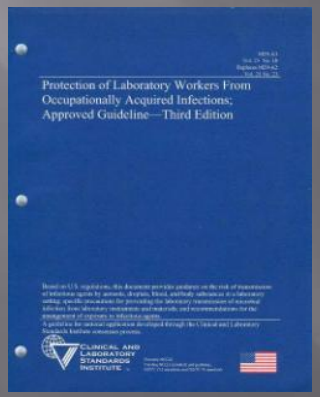
- Serve as an information resource to assist public health laboratories with implementing the activities outlined in the ELC
- Inform and assist in establishing a repository for new and existing biosafety and biosecurity tools and promoting their use
- Advise on the development of a “community of practice” for biosafety officers in member laboratories
- Collaborate with APHL staff and partners to develop and deliver biosafety and biosecurity competency based training materials, including convening workshops for biosafety officers
- Promote APHL’s position statement on biosafety and collaborate with partners to encourage a culture of biosafety and biosecurity as part of each laboratory’s quality management system

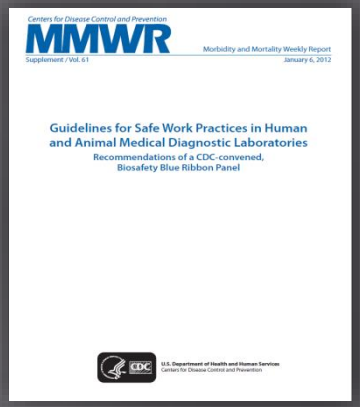
What do clinical labs need?

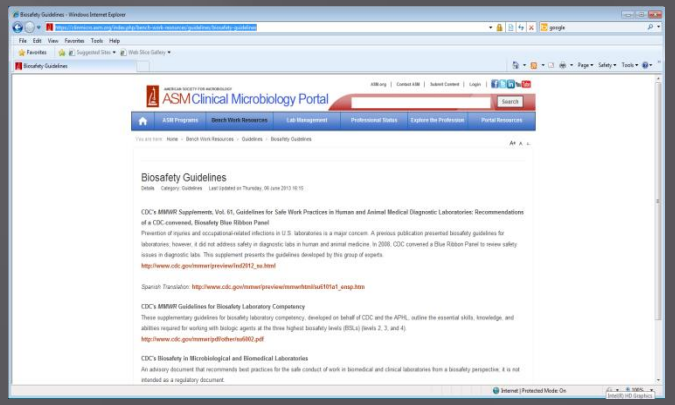
- National standards and guidance (checklist)
- Incentive to get this accomplished and recognition of accomplishment
- Training and education
- Simple, comprehensive tools to make this achievable
- Engagement of all lab sections
- Commitment from administration/leadership
- National resource to report accidents and exposures
- Assistance with difficult issues, ex. Medical waste management

There are good biosafety resources

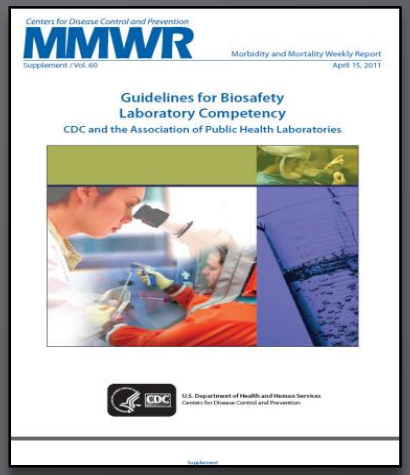
- But there is not one simple and easy to follow source for all the information needed to build a “culture of biosafety”
- There needs to be more consensus building on biosafety issues, for example:
  - Wearing gloves in the microbiology lab to read plates
  - How to do a risk assessment







Clinical labs need to adopt biosafety competencies as part of their annual competency program



Field	Entry Level	Midlevel	Senior level
Academia or research	Technician, research associate, or specialist	Principal investigator, laboratory manager, postdoctoral student, or senior or staff scientist	Principal investigator or branch or division manager
Clinical setting	Laboratory scientist or medical technologist	Chief/head scientist or medical technologist, laboratory specialist, or laboratory manager	Laboratory manager, chief technologist, or hospital or clinic director

Report an Incident

Report laboratory-acquired infections here!

Report-LAI is a website dedicated to the anonymous reporting of laboratory incidents that may result in a laboratory-acquired infection. As a joint project of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), this website's goal is to provide an easy and secure means of collecting data that can be analyzed to help you make your workplace safer.

In addition to being able to enter data about incidents in biological laboratories, site visitors will have full access to standardized reports generated from all data entered here.

Report-LAI is a simple, voluntary and anonymous reporting system. At no time will any information be collected on forms or by any other means that will identify you.

To report a laboratory incident, click here.

Our Mission

Laboratory biosafety is in everyone's best interest. The more we know about accidents, exposures to potentially infectious agents, any resulting laboratory-acquired infections, and patient outcomes, the better prepared we will be to respond to situations appropriately.

Click here to read more.

About the Joint Project

During revision of the CDC/NIH publication entitled *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), it was necessary to make decisions about inclusion of pertinent agent summary statements in the 5th Edition.

Click here to read more.

Why You Should Participate

Report-LAI-participating individuals or institutions cannot be identified, whether they have submitted an incident report or are viewing standardized reports, alerts, and safety trend analyses.

Click here to read more.

The future for biosafety in labs

- By accomplishing what is outlined in these slides, labs will demonstrate improvement from current status
- Labs will have active biosafety programs
- Over time, other quality indicators can be measured, for example:
  - Risk assessments completed
  - Risk assessments revised and reasons for revision
  - Reduction in exposures
  - Competencies completed